



PATENT
Docket No. 263742000201
Client Reference No.: REP06021US

CERTIFICATE OF MAILING BY "EXPRESS MAIL"

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Dated: April 8, 2004

Signature: Tia Zimmerman

(Tia B. Zimmerman)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Bruce J. ROSER et al.

Serial No.: 09/836,625

Filing Date: April 16, 2001

For: METHODS OF PREVENTING
AGGREGATION OF VARIOUS
SUBSTANCES UPON REHYDRATION
OR THAWING AND COMPOSITIONS
OBTAINED THEREBY

Examiner: M. Davis

Group Art Unit: 1642

**SUPPLEMENTAL INFORMATION DISCLOSURE
STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98**

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO-1449. Copies of the documents are also submitted herewith. I hereby certify that each item of information was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Supplemental Information Disclosure Statement. The Examiner is requested to make these documents of record.

This Supplemental Information Disclosure Statement is submitted:

- ☐ With the application; accordingly, no fee or separate requirements are required.
- ☐ Before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114. However, if applicable, a certification under 37 C.F.R. § 1.97(e)(1) has been provided.
- ☐ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required. However, if applicable, a certification under 37 C.F.R. § 1.97(e)(1) has been provided.
- ☐ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
 - ☐ A fee is required. A check in the amount of ___ is enclosed.
 - ☐ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above; accordingly; no fee is believed to be due.
- ☒ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a check in the amount of ___ is enclosed.
 - ☒ A Certification under 37 C.F.R. § 1.97(e) is provided above and a Fee Transmittal form (PTO/SB/17 is attached to this submission in duplicate.)


Applicants would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

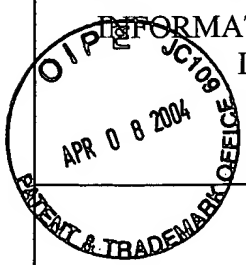
In the unlikely event that the transmittal form is separated from this document and the Patent Office determines that an extension and/or other relief (such as payment of a fee under 37 C.F.R. §1.17(p)) is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing 263742000201. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: April 8, 2004

Respectfully submitted,

By: 
Shantanu Basu
Registration No. 43,318

Morrison & Foerster LLP
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Palo Alto, California 94304-1018
Telephone: (650) 813-5995
Facsimile: (650) 494-0792

Form PTO-1449  INFORMATION DISCLOSURE CITATION IN AN APPLICATION (Use several sheets if necessary)	Docket Number 263742000201	Application Number 09/836,625
	Applicant Bruce J. ROSER et al.	
	Filing Date April 16, 2001	Group Art Unit 1642
	Mailing Date April 8 2004	

U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	07/03/1984	4,457,916	Hayashi et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO
	2.	03/19/1997	EP 0 762 897	Europe			

OTHER DOCUMENTS (including author, title, Date, Pertinent Pages, Etc.)

Examiner Initials	Ref. No.	Title
	3.	Arakawa, T. et al. (1993). "Factors Affecting Short-Term and Long-Term Stabilities of Proteins," <i>Advanced Drug Delivery Reviews</i> 10:1-28.
	4.	Carpenter, J. F. et al. (1990). "Comparison of Solute-Induced Protein Stabilization in Aqueous Solution and in the Frozen and Dried States," <i>J. Dairy Sci.</i> 73(12):3627-3636.
	5.	Colaco, C.A.L. S. et al. (1994). "Chemistry of Protein Stabilization by Trehalose" Chapter 14 <i>In Formulation and Delivery of Proteins and Peptides</i> , Cleland, J. L. et al. eds. American Chemical Society: Washington, DC. pp. 222-240.
	6.	Crowe, J.H. et al. (1990). "Are Freezing and Dehydration Similar Stress Vectors? A Comparison of Modes of Interaction of Stabilizing Solutes with Biomolecules," <i>Cryobiology</i> 27:219-231.
	7.	Darnell, J. et al. eds. (1986). <i>Molecular Cell Biology</i> Scientific American Books, Inc. pp. 59.
	8.	De Young, L.R. et al. (1993). "Aggregation and Denaturation of Apomyoglobin in Aqueous Urea Solutions," <i>Biochemistry</i> 32:3877-3886.
	9.	Heitefuss, R. et al. (1959). "The Stabilization of Extracts of Cabbage Leaf Proteins by Polyhydroxy Compounds for Electrophoretic and Immunological Studies," <i>Archives of Biochemistry and Biophysics</i> 85:200-208.
	10.	Lee, J.C. et al. (1981). "The Stabilization of Proteins by Sucrose," <i>The Journal of Biological Chemistry</i> 256(14):7193-7201.
	11.	Manning, M.C. et al. (1989). "Stability of Protein Pharmaceuticals," <i>Pharmaceutical Research</i> 6(11):903-917.

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

Form PTO-1449

Docket Number 263742000201

Application Number 09/836,625

INFORMATION DISCLOSURE CITATION IN AN APPLICATION

(Use several sheets if necessary)

Applicant

Bruce J. ROSER et al.

Filing Date April 16, 2001

Group Art Unit 1642

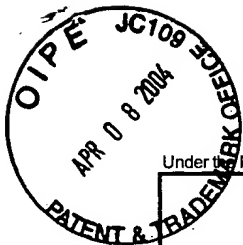
Mailing Date April 8 2004

- | | |
|-----|---|
| 12. | Newman, Y.M. et al. (1993). "The Role of Trehalose and Other Carbohydrates in Biopreservation," <i>Biotechnology and Genetic Engineering Reviews</i> 11(5):263-294. |
| 13. | Paborji, M. et al. (1994). "Chemical and Physical Stability of Chimeric L6, a Mouse-Human Monoclonal Antibody," <i>Pharmaceutical Research</i> 11(5):764-771. |
| 14. | Pikal, M.J. (1991). "Freeze-Drying of Proteins: Part II: Formulation Selection," <i>Pharmaceutical Technology International</i> pp. 40-43. |
| 15. | Prestrelski, S.J. et al. (1993). "Dehydration-Induced Conformational Transitions in Proteins and Their Inhibition by Stabilizers," <i>Biophysical Journal</i> 65:661-671. |
| 16. | Schwartz, P.L. et al. (1973). "The Aggregation of [¹²⁵ I] Human Growth Hormone in Response to Freezing and Thawing," <i>Endocrinology</i> 92(6):1795-1798. |

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.



04-12-04

ATZ 11600-8 Image

PTO/SB/21 (08-03)

Approved for use through 07/31/2006, OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM (to be used for all correspondence after initial filing)		Application Number	09/836,625
		Filing Date	April 16, 2001
		First Named Inventor	Bruce J. ROSER
		Art Unit	1642
		Examiner Name	M. Davis
Total Number of Pages in This Submission	10 + 16 Refs.	Attorney Docket Number	263742000201

ENCLOSURES (Check all that apply)

<input checked="" type="checkbox"/> Fee Transmittal Form (1 page in duplicate) <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement (3 pages) <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): 1. Form PTO-1449 (2 pages in duplicate) 2. References (16) 3. Return receipt postcard
Remarks		

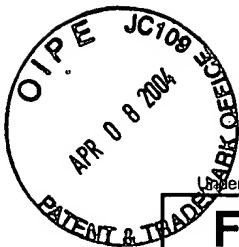
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	MORRISON & FOERSTER LLP Shantanu Basu - 43,318	(Customer No. 25226)
Signature		
Date	April 8, 2004	

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Dated: April 8, 2004

Signature: (Tia B. Zimmerman)



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

FEE TRANSMITTAL for FY 2004

Effective 10/01/2003, Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 180.00

Complete if Known

Application Number 09/836,625
Filing Date April 16, 2001
First Named Inventor Bruce J. ROSER
Examiner Name M. Davis
Art Unit 1642
Attorney Docket No. 263742000201

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number 03-1952

Deposit Account Name Morrison & Foerster LLP

The Director is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet.	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for <i>ex parte</i> reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	180.00
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$) 180.00

FEE CALCULATION

1. BASIC FILING FEE

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) (\$) 0.00

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

		Extra Claims		Fee from below		Fee Paid
Total Claims	11	-42** =	0	x	18	= 0.00
Independent Claims	3	-5** =	0	x	86	= 0.00
Multiple Dependent					290	= 0.00

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1202	18	2202	9	Claims in excess of 20	
1201	86	2201	43	Independent claims in excess of 3	
1203	290	2203	145	Multiple dependent claim, if not paid	
1204	86	2204	43	** Reissue independent claims over original patent	
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent	

SUBTOTAL (2) (\$) 0.00

**or number previously paid, if greater; For Reissues, see above

SUBMITTED BY

Name (Print/Type) Shantanu Basu

Registration No. (Attorney/Agent) 43,318

(Complete if applicable)

Telephone (650) 813-5995

Signature

Date

April 8, 2004